



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/915,150

07/25/2001

Gary R. DelDuca

47097-01080

6442

30223

7590

03/17/2009

NIXON PEABODY LLP
161 N. CLARK STREET
48TH FLOOR
CHICAGO, IL 60601-3213

EXAMINER

CHAWLA, JYOTI

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

03/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GARY R. DELDUCA,
STEPHEN L. GOULETTE,
VIINOD K. LUTHRA, and
MARCUS C. MERRIMAN

Appeal 2009-1245
Application 09/915,150
Technology Center 1700

Decided:¹ March 17, 2009

Before CHARLES F. WARREN, CATHERINE Q. TIMM, and
LINDA M. GAUDETTE, *Administrative Patent Judges*.

TIMM, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the Decided Date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1-37, 87-90, and 161-171. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

The invention relates to low- or no-oxygen modified atmosphere packages (MAPs) and a method for manufacturing MAPs for storing food, particularly raw meats. (Spec. 2, ll. 5-8). The MAP of the present invention includes an exterior layer or an exterior package, which is impermeable to oxygen, and an inner package or layer, which is permeable to oxygen. (Spec. 8, ll. 20-22; 9, ll. 20-22). The low-oxygen modified atmosphere within the package includes a carbon monoxide (CO) gas mixture, having a CO content of about 0.1 to about 0.8 % by volume. (Spec. 10, l. 30 to 11, l. 1). Exposure to CO provides causes carboxymyoglobin to form, which provides the meat with a red color similar to the color of oxymyoglobin that otherwise forms when fresh raw meat is exposed to oxygen. (Spec. 12, ll. 14-28). As such, the meat may be displayed at retail more quickly than typical low-oxygen MAPs, which require subsequent exposure to oxygen during a "seasoning" process. (Spec. 11, l. 29 to 12, l. 2).

The exterior package is used during storage but is removed at a retail location to release CO, and allow oxygen to access the meat through the permeable interior package or layer. (Spec. 12, ll. 4-12). As such, the carboxymyoglobin converts to oxymyoglobin (of similar color to the carboxymyoglobin) and then to metmyoglobin, which causes the natural brown color that fresh meat would turn if it was exposed to air. (Spec. 12, ll. 2-12). Thus, using the MAP of the present invention, meat previously stored

under low-oxygen modified atmosphere conditions and subsequently displayed in air at retail would turn brown at approximately the same rate as unstored, freshly-cut meat displayed at retail at the same time the stored meat is displayed. (Spec. 12, ll. 7-10). Claim 1 is illustrative of the subject matter on appeal:

1. A method of manufacturing a modified atmosphere package, the method comprising:

supplying a first package including a non-barrier portion substantially permeable to oxygen;

placing a retail cut of raw meat within the first package, the meat having meat pigment;

sealing the first package;

supplying a second package substantially impermeable to oxygen;

covering the first package with the second package without sealing the second package so as to create a pocket between the first and second packages;

supplying a mixture of gases into the pocket, the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;

removing oxygen from the pocket so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat; and

sealing the second package, wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package.

The Examiner relies on the following prior art references to show unpatentability:

| | | |
|-------------------------|--------------|---------------|
| Koch et al. | US 3,459,117 | Aug. 5, 1969 |
| Verbruggen ² | DE 1935566 A | Jan. 22, 1970 |
| Woodruff et al. | US 4,522,835 | Jun. 11, 1985 |
| Breen et al. | US 5,711,978 | Jan. 27, 1998 |
| Shaklai | US 6,042,859 | Mar. 28, 2000 |
| Carr et al. | US 6,054,153 | Apr. 25, 2000 |

The Examiner maintains the following rejections:

1. Claims 1-6, 8-11, 13-26, 28-30, 32-37, 87-90, 161, 162, and 164-171 rejected under 35 U.S.C. § 103(a) as obvious over Carr et al. (“Carr”) in view of Woodruff et al. (“Woodruff”), Koch et al. (“Koch”), and Shaklai; and

2. Claims 1, 2, 5-10, 12-15, 18-23, 25-29, 31-34, 36-37, 87-90, and 161-171 rejected under 35 U.S.C. § 103(a) as obvious over Breen et al. (“Breen”) in view of Woodruff, Koch, Shaklai, and Verbruggen.

Appellants do not present separate arguments for any particular claim with respect to either rejection. (*See generally* App. Br.). Therefore, we decide this Appeal on the basis of representative independent claim 1 for both the first rejection and the second rejection. *See* 37 C.F.R. § 41.37(c)(1)(vii) (“When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal

² The English translation of Verbruggen prepared for the USPTO by John M. Koytcheff (PTO 2007-6908 September 14, 2007) is made of record in the Office Communication mailed January 7, 2008. However, the Examiner’s rejection relies on the English Abstract made of record in the Office Communication mailed May 7, 2003.

with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone.”).

I. ESTABLISHMENT OF A PRIMA FACIE CASE OF OBVIOUSNESS

A. ISSUE ON APPEAL

Appellants contend that one of ordinary skill in the art would not have used a modified atmosphere containing CO, as taught by Woodruff, Koch, Shaklai, or Verbruggen with packaging taught by Carr or Breen, because it was “the understanding of those of ordinary skill in the art at the time of the present invention that CO ‘fixes’ the color of the meat pigment,” which can mask spoilage. (App. Br. 8). Appellants also contend that “none of the references of Shaklai, Koch, Woodruff or Hermann [sic, Verbruggen] . . . teaches or suggests the claimed limitation of ‘wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package.’” (App. Br. 10.)

The Examiner interprets Appellants’ arguments as “it was not known in prior art that removal of modified atmosphere comprising CO will cause the color of the meat pigment on the surface of the meat to turn brown (i.e., change from the bright red carboxymyoglobin color to brown metmyoglobin color)” and finds this argument unsubstantiated in light of the contrary teachings of the prior art. (Ans. 18). The Examiner also contends that since the method taught by the combination of references has the same steps and includes a concentration of CO that falls within the claimed range, “it follows that the raw meat will ‘turn brown’ in the same or comparable time

period as the Appellant's [sic, Appellants'] claimed invention." (Ans. 19, *see* Ans. 21 and 22).

A first issue on appeal arising from the contentions of Appellants and the Examiner is: have Appellants shown that the Examiner reversibly erred in establishing a *prima facie* case of obviousness? Specifically, did the Examiner reversibly err in determining that one of ordinary skill in the art would have been motivated to include a CO-containing gas mixture, such as taught by Woodruff, Koch, Shaklai and Verbruggen, in a packaging arrangement as taught by Carr and Breen and would the ordinary artisan have understood from the teachings of Woodruff, Koch, Shaklai and Verbruggen that "the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package"? We answer this question in the negative.

B. FACTUAL FINDINGS

The following Findings of Fact (FF) are relevant to deciding the above identified issue on appeal:

1. Appellants' Specification does not define the phrase "natural time period." (*See generally* Spec.).
2. Appellants' Specification does not define the phrase "turns brown." (*See generally* Spec.).
3. Appellants' Specification states that
the gas mixture used in the modified atmosphere packaging of the present invention, after removal, allows the carboxymyoglobin to convert to oxymyoglobin and then to metmyoglobin (brown) in a natural time period. Since the package is opened (at least substantially permeable to oxygen)

before retailing, the carbon monoxide level is lost to the atmosphere, thus allowing the conversion of carboxymyoglobin to oxymyoglobin by using the oxygen from the air. The meat, following storage in the gas mixture of the present invention, surprisingly allows the meat pigment to convert to metmyoglobin in a similar fashion as fresh, raw meat in a retail environment. In other words, the meat pigment tends to turn brown in a natural time period. Thus, most importantly the gas mixture of the present invention does not “fix” the color of the meat pigment to red as with higher levels of carbon monoxide.

(Spec. 12, ll. 2-12).

4. The Examples of Appellants’ Specification include “Inventive Examples” which are opened for display in air after being stored in an environment of 0.4% vol. CO, 30% vol. carbon dioxide, and 69.6% vol. nitrogen for 7, 14, 21 or 35 days (depending upon the cut of the meat) at two storage temperatures. (Spec. 18, ll. 26-29 and 20, ll. 4-8).

5. The Examples of Appellants’ Specification also include “Comparative Examples” which are four hour old cuts of meat displayed in air along side the “Inventive Examples.” (Spec. 18, ll. 25-26 and 30-31; 20, ll. 1-2).

6. The Comparative Examples of Appellants’ Specification turn to an “unacceptable color” anywhere from 2.6 days for a tenderloin to 6.2 days for a striploin (strip steak). (Spec. 24, Table 2). Thus, according to Appellants’ Specification, the natural time period may be anywhere from 2.6 to 6.2 days, depending upon the cut of meat.

7. The Fourth DelDuca Declaration states that the term “turns brown” “means that the piece of meat has some brown, but does not mean that the piece of meat has to be 100% brown.” (Fourth Deluca Decl. ¶ 6).

8. Appellants argue that one of ordinary skill in the art would expect “beefsteak would turn brown in about 2-3 days, depending upon the cut of meat.” (App. Br. 14; *see* Fourth DelDuca Decl. ¶ 7 (4 days for strip steak and 1 day for tenderloin)).

9. The Examiner has indicated that “meat may generally take 3 or more days to naturally turn brown (allowing for the variability in natural conditions [such as geographical location, season, size of meat and type of meat] discussed above).” (Ans. 17).

10. Shaklai teaches that “hemoglobin and myoglobin bind carbon monoxide much more strongly than oxygen.” (Shaklai, col. 5, ll. 66-67; *see* col. 6, ll. 26-35).

11. Shaklai teaches that exposure to a 100% CO modified atmosphere for 30 minutes “maintained a wine-red color for at least 24 hours following exposure,” but exposure to 100% CO modified atmosphere for 21 days causes the surface of the meat to turn brown by day 14 after exposure to air at 4°C. (Shaklai, col. 8, ll. 37-49 and col. 9, ll. 40-49).

12. Shaklai also teaches that “[t]he total CO treatment of the meat throughout its thickness also enables meat which has been treated according to the present invention to maintain a pleasing color for extended periods of time after the meat has been removed from the packaging or container in which it was treated.” (Shaklai, col. 8, ll. 13-18). In other words, with less saturation or lower concentration of CO, color may not be retained for an extended period of time after removal.

13. Woodruff teaches that oxygen competes with CO for reactive sites of reduced myoglobin. (Woodruff, col. 1, ll. 54-58).

14. Woodruff teaches a modified atmosphere of 0.1-3% vol. CO, at least about 10% vol. carbon dioxide, and the balance nitrogen or other inert gas. (Woodruff, col. 1, ll. 48-51; col. 2, ll. 2-9).

15. Woodruff teaches that carboxymyoglobin is “stable under refrigerated conditions for long periods of time, such as two to four weeks” when “maintained under these conditions.” (Woodruff, col. 3, ll. 1-4 and 27-30).

16. Woodruff provides no examples of meat stored in the CO, carbon dioxide and nitrogen atmosphere, and subsequently exposed to air. (*See generally* Woodruff).

17. However, Woodruff does teach that after exposure to a modified atmosphere of 0.5% vol. CO for two days, the meat was exposed to a second modified atmosphere of 55% carbon dioxide and 15% oxygen, in which “the beefsteak retained its good red color” six days later. (Woodruff, col. 4, l. 34-54).

18. Woodruff also teaches that optimum amounts of CO vary with type of meat, the method used to deoxygenate, and the conditions maintained before exposure to CO. (Woodruff, col. 4, ll. 17-23).

19. Koch teaches carboxymyoglobin is more stable than oxymyoglobin, thus the iron oxidizes (to form metmyoglobin) “only after a considerable number of days exposure of the meat to oxygen.” (Koch, col. 2, ll. 3-6).

20. Koch also teaches meat exposure to “relatively small quantity” (0.08cc/sq. in) of 100% CO. (Koch, col.2, ll. 18-22; col. 3, ll. 42-46).

21. Koch also teaches a permeable and impermeable layer packaging using a modified atmosphere containing CO between the pair of layers. (Koch, col. 1, ll. 13-20).

22. Koch teaches that “meat will retain a saleable red color for as long as ten days when covered with the cover herein described for the first seven days and with a conventional cover for the remaining 3 days.” (Koch, col. 3, ll. 10-13). Thus, Koch teaches that meat only retains its red color for 3 days after removal of the CO.

23. Koch teaches that the packaging can be used with individual cuts as well as primal cuts. (Koch, col. 3, ll. 13-17 and 38-41).

24. Koch teaches using a package with a small amount of CO to reduce human exposure to CO. (Koch, col. 3, ll. 42-48).

25. Verbruggen teaches storage with pure CO or a mixture of CO with reduction gases or neutral gases, such as nitrogen and carbon dioxide. (Verbruggen, translation, at 3).

26. However, Verbruggen teaches that “[i]f the foodstuffs are brought back to the normal or standard atmosphere, entire free gases escape into the atmosphere so that the treatment in accordance with the invention does not leave any noticeable traces” and that “excess amount of gasses, which do not react with the foodstuff, can automatically be removed from the latter by means of aeration or ventilation.” (Verbruggen, translation, at 4).

27. Verbruggen teaches that compound formed when CO combines with hemoglobin or myoglobin (i.e., carboxymyoglobin) “very pronouncedly resembles the color of the compounds, which impart the natural color to the meat” (Verbruggen, translation, p. 3).

28. Woodruff, Koch, Shaklai, and Verbruggen teach that the carboxymyoglobin formed from exposure to CO causes the meat to have a red color that is pleasing to a consumer. (Koch, col. 2, ll. 3-4; Woodruff, col. 2, l. 58 to col. 3, l. 4; col. 8, ll. 19-21; Shaklai, col. 5, ll. 13-18, col. 8, ll. 18-22; Verbruggen, translation, at 3).

29. Woodruff, Shaklai, and Verbruggen also teach that the use of a low-oxygen modified atmosphere prevents the growth of aerobic bacteria. (Woodruff, col. 3, ll. 5-14; Shaklai, col. 6, ll. 31-35; Verbruggen, translation, at 3; *see also* Carr, col. 1, ll. 38-45; Breen, col. 1, ll. 29-30).

30. Appellants' evidence indicates that Norway has allowed meat packed in up to 0.5% vol. CO since the mid-eighties. (Hunt Decl., Exhibit B, Pactiv GRAS Notice, at 67; Exhibit 10, Sorheim et al., "The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide," *Meat Science* 52, 157-164 (1999) (hereinafter "Sorheim"), at 157).

31. Carr and Breen teach a low-oxygen modified atmosphere packaging, with an inner layer having improved permeability and an outer layer that is impermeable, that is to be opened and exposed air prior to retail display. (Carr, col. 2, ll. 48-58, col. 6, ll. 41-45; Breen, col. 2, ll. 43-59).

32. The Pactiv GRAS Notice to the U.S. Food and Drug Administration ("FDA") describes that "[a] possible negative aspect" of using CO in a modified atmosphere package is "a concern that the consumer might misjudge the product, because the microbiological status may be masked by the stable cherry red carboxymyoglobin colour." (Hunt Decl., Exhibit B, Pactiv GRAS Notice, at 65, 132, 149). However, this statement does not specifically refer to meat remaining red after removal of the CO

atmosphere and exposure to air. (*See generally* Hunt Decl., Exhibit B, Pactiv GRAS Notice).

33. While various references in the Pactiv GRAS Notice states that “the stable cherry-red colour can last beyond the microbiological shelf life of the meat and thus mask spoilage,” citing “Kropf 1980” (Hunt Decl., Exhibit B, Pactiv GRAS Notice, 78, 107, 149), the references are directed to microbial and color comparisons taken only under storage conditions. (Hunt Decl., Exhibit B, Pactiv GRAS Notice, 107-108, 148-149).

34. The Pactiv GRAS Notice describes the condition where meat during storage in a modified atmosphere containing CO was exposed to small amounts of air to simulate a leaking package, in which, after 2 days (for ground meat) and 5 days (for loin/chop cuts), all showed less red color after exposure. (Hunt Decl., Exhibit B, Pactiv GRAS Notice, 124-125).

35. Sorheim describes the “possibility that the colour stability can exceed the microbiological shelf life, with the risk of masking spoilage,” but only provides data measuring the color under conditions of continued storage in a CO environment, not after removal of the CO environment and exposure to air. (Sorheim, at 159-161, 163).

36. In the Whirlpool/FDA letters, the FDA requests data on whether the “the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated” but does not provide any information regarding meat after removal of the CO environment and exposure to air. (Exhibit 7, “1962 letters between FDA and Whirlpool Corporation”).

37. The Kalsec, Inc. Petition raises concern about the Pactiv GRAS Notice because of color masking effects in anaerobic packaging

environments (i.e., when not exposed to air) due to abuse of storage conditions and questions the authority of the FDA to allow the use of CO in Pactiv product despite FDA regulations. (Exhibit 8, FDA Petition by Kalsec, Inc.). However, the Petition does not specifically mention concerns about meat after removal of the CO environment and exposure to air. (*See generally* Exhibit 8, FDA Petition by Kalsec, Inc.).

C. PRINCIPLES OF LAW

“Section 103 forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 127 S. Ct. at 1734 (“While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.”).

“[T]he question is whether there is something in the prior art as a whole to suggest the *desirability*, and thus the obviousness, of making the combination,” not whether there is something in the prior art as a whole to suggest that the combination is the *most desirable* combination available. *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004). Rather, “any need or problem known in the field of endeavor at the time of invention and

addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR*, 127 S. Ct. at 1742; *In re Kemps*, 97 F.3d 1427, 1430 (Fed. Cir. 1996) (“the motivation in the prior art to combine the references does not have to be identical to that of the applicant to establish obviousness.”).

In particular, an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 127 S. Ct. at 1741. In considering the question of the obviousness of the claimed invention in view of the prior art relied upon, we are guided by the basic principle that the question under 35 U.S.C. § 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made. *See Merck & Co. v. Biocraft Labs.*, 874 F.2d 804, 807 (Fed. Cir. 1989); *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (“The test for obviousness is not . . . that the claimed invention must be expressly suggested in any one or all of the references.”).

During examination, “claims . . . are to be given their broadest reasonable interpretation consistent with the specification, and . . . claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

Optimization of a variable which is recognized in the prior art to be a result effective variable would ordinarily be within the skill in the art. *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980).

D. ANALYSIS

Applying the preceding legal principles to the Factual Findings in the record of this appeal, we determine that the Examiner has established a prima facie case of obviousness.

The prior art provides sufficient motivation for one of ordinary skill in the art to use a CO containing gas mixture, such as taught by Woodruff, Koch, Shaklai, and Verbruggen in a low-oxygen atmosphere package as taught by Carr or Breen. The prior art exhibits many examples of those of ordinary skill in the art using CO in a low-oxygen MAP for the packaging of meat. (FF 11, 12, 14, 17, 20, and 25). Additionally, the evidence provided by Appellants indicates that CO in a modified atmosphere has been used for packaging meat in Norway since the mid-eighties. (FF 30).

Even if it was known that the CO modified atmosphere has the drawback of fixing the color of the red meat, the proposed combination need only suggest that using CO is desirable to make the combination obvious, not necessarily the most desirable alternative. *Fulton*, 391 F.3d at 1200; *KSR*, 127 S. Ct. at 1742. Thus, Appellants have not shown that, even with the knowledge of one of ordinary skill in the art that the color of meat is fixed, one of ordinary skill in the art would not have been motivated to use CO in a gas mixture as taught by Woodruff, Koch, Shaklai, and Verbruggen in a modified atmosphere packaging as taught by Carr and Breen.

Woodruff, Koch, Shaklai, and Verbruggen teach using CO for the particular reason that the carboxymyoglobin formed from the reaction has a preferable color (i.e., similar to that of fresh meat displayed in oxygen). (FF 27 and 28). As such, the prior art teaches using CO for the same purpose as the present invention, for the benefit it provides to the color of the meat. (*See*

Spec. 12, ll. 2-12). However, any recognized problem may provide sufficient motivation to one of ordinary skill in the art for using a CO gas mixture as the low-oxygen modified atmosphere in the packages of Carr and Breen. *KSR*, 127 S. Ct. at 1742. Thus, the prior art provides sufficient motivation for one of ordinary skill in the art to use CO in the modified atmosphere package taught by Carr or Breen.

Further, Carr and Breen both teach opening the packaging to air after storage of the meat, but prior to retail sale. (FF 31). We can agree that one of ordinary skill in the art would have believed that meat would be “fixed” in color so as to mask spoilage *while it remains in a modified atmosphere containing CO*. However, we find that the evidence does not support the contention that one of ordinary skill in the art would have believed the same for meat that is subsequently *removed from the CO environment*.

For example, Verbruggen specifically states that, through ventilation, the CO-containing gases can escape and the meat can be brought back to a normal atmosphere without leaving “any noticeable traces.” (FF 26). In other words, the effects of CO are removed upon proper ventilation of the meat. Similarly, Woodruff suggests that meat will retain the red color of carboxymyoglobin while it remains in the CO-modified atmosphere for as long as “two to four weeks.” (FF 15). However, since Woodruff also teaches that, in one example, the meat stayed red for six days upon subsequent exposure to an environment that did not contain CO (FF 17), Woodruff would have suggested to one of ordinary skill in the art that carboxymyoglobin converted to metmyoglobin within six days of the CO environment being removed. Similarly, Shaklai and Koch also teach that, upon removing the modified atmosphere and subsequently exposing the

meat to air, the carboxymyoglobin eventually converts to metmyoglobin, and the meat will turn brown. (FF 11 and 22). Thus, any teaching directed to meat remaining in a CO-containing environment does not supersede or contradict the teachings directed to the effect on meat after the CO-containing conditions are removed. *Merck*, 874 F.2d at 807; *Keller*, 642 F.2d at 425.

The prior art teaches that myoglobin has a stronger affinity for CO than oxygen and that carboxymyoglobin is stable. (FF 10, 13, 19). However, this teaching also does not contradict the prior art's further teachings that carboxymyoglobin converts to metmyoglobin upon exposure to air. *Id.*

The evidence provided by Appellants also does not contradict the findings of the prior art. Rather, the evidence provided by Appellants suggests that one of ordinary skill in the art would have been concerned about meat color masking spoilage only *while remaining* in the CO environment. (FF 32-37). Appellants have not directed our attention to any portion of the provided evidence that one of ordinary skill in the art would have expected the color to remain fixed specifically *upon removal of the meat from the CO environment and exposure to air*, as would be the case if the modified atmospheres taught by Woodruff, Koch, Shaklai, or Verbruggen were included in the packaging taught by Carr or Breen.

According to claim 1, "the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package." (Claim 1). Appellants' Specification does not describe any active steps taken to adapt the carbon monoxide in the

gas mixture to achieve this result. Rather, the meat turns brown as the natural consequence of exposing the meat to air rather than CO. (FF 3). Thus, this limitation requires only that the CO is capable of being removed to such an extent that the color of the meat turns brown in a natural time period when the second package is removed. We also take note that claim 1 does not include an active step of removing the second package. (*See* claim 1).

The claim does not recite that the meat pigment must “turn brown” to any particular degree. (FF 1-2). Appellants’ Specification describes only that the carboxymyoglobin, which has a red color, converts to oxymyoglobin, which also has a red color, and then to metmyoglobin, which is brown. (FF 3). The carboxymyoglobin (red) to metmyoglobin (brown) reaction occurs only from releasing the CO-containing gas mixture in which the meat was stored and exposing the meat to air. (FF 3). The inventor further argues that the term “turns brown” means that the meat has “some brown” but not 100% brown. (FF 7). Thus, we agree with the Examiner that the phrase “turns brown” includes any amount or any extent to which the meat turns brown.

Claim 1 also does not limit what constitutes a “natural time period” for meat to “turn brown.” (*See* claim 1). Appellants and the Examiner suggest anywhere from 1-4 days is a reasonable amount of time for a cut of meat to turn brown, depending upon the cut of meat. (FF 8-9). Yet, the “Comparative Examples” of Appellants’ Specification, which are displayed in air in a retail environment from 4 hours old, show an “unacceptable color” between 2.6 and 6.2 days depending upon the cut of meat. (FF 4-6). Since claim 1 does not designate the “natural time period” by a particular cut of

meat or under any other specific conditions other than CO concentration, the broadest reasonable interpretation of Appellants' Specification suggests that the "natural time period" for meat to turn brown may be up to as many as 6.2 days. *Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d at 1364.

Woodruff (6 days), Koch (3 days), and Shaklai (24 hours) provide examples where meat turned brown within the claimed "natural time period" of 6.2 days upon removal of the CO environments. (FF 11, 17 and 22). Thus, the prior art teaches "the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package."

Further, Shaklai teaches that the amount of time the meat is exposed to CO affects the amount of time it takes for meat to turn brown upon subsequent exposure to air. (FF 11). Shaklai also suggests that the retention of the red color may only be achieved by 100% saturation of the meat with pure CO. (FF 12). Appellants' Specification states that one of ordinary skill in the art would have expected the meat to remain red "with higher levels of carbon monoxide" (FF 3), suggesting that carbon monoxide utilized in low amounts as taught by Woodruff and Koch would not have been expected to result in meat remaining red for as long. (FF 14 and 20). Similarly, Woodruff teaches varying the optimum amount of CO based on various conditions. (FF 18). Thus, the amount of CO would be a result effective variable that would have been obvious for one of ordinary skill in the art to adjust to achieve a desired result. *Boesch*, 617 F.2d at 276. Thus, one of ordinary skill in the art would have expected the meat to turn brown in a

“natural time period” by adjusting the exposure time and maintaining a low concentration of CO in the modified atmosphere.

Appellants’ Specification cites no conditions, other than the concentration of CO and the subsequent removal of the CO, that cause the meat packaged according to the present invention to turn brown in a natural time period. (FF 3). The concentrations taught by Woodruff (0.1-3% vol. CO) encompass the claimed range of 0.1-0.8% vol. CO. (FF 14 and 25; Claim 1). Therefore, a system using a CO concentration taught by Woodruff and capable removing the modified atmosphere and exposure to air as taught by Carr and Breen, accordingly would cause the meat to turn brown in a natural time period as claimed.

II. SECONDARY INDICIA OF NON-OBVIOUSNESS

A. ISSUE ON APPEAL

Appellants contend that even if the Examiner has established a prima facie case of obviousness, that the present invention is not obvious because: (a) the commercial embodiment of the present invention was the first product using carbon monoxide in meat packaging allowed by the U.S. Food and Drug Administration (“FDA”) since establishment of a 1962 ban on the use of CO for meat packaging; (b) the present invention addresses a long-felt need in the meat-packaging industry; and (c) the commercial embodiment of the present invention has demonstrated commercial success. (App. Br. 18-25).

The Examiner contends (a) that FDA regulations are “not relevant to issue of obviousness in this case because Patent law is independent from FDA regulatory law,” (b) that Appellants have not provided sufficient evidence to establish a long-felt need in the meat-packing industry, and (c)

that factors other than the claimed invention may have alternatively contributed to the commercial success of Appellants' product. (Ans. 23-25).

A second issue on appeal arising from the contentions of Appellants and the Examiner is: have Appellants provided sufficient evidence of non-obviousness to rebut the prima facie case of obviousness established by the Examiner? We answer this question in the negative.

B. FACTUAL FINDINGS

The following additional Findings of Fact are relevant to deciding the above identified issue on appeal:

38. The Hunt Declaration states that:

Prior to Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO, there was a need in the industry to provide a solution that: (a) reduced the seasoning period (the critical time meat is exposed to low partial pressures of oxygen, which can seriously damage the pigment chemistry); (b) formed consistently a normal bloomed color with meats whose pigment is sensitive to metmyoglobin formation; and (c) avoided the fixing of too stable of a meat color, which can be unsafe and potentially dangerous, if the color stability was greater than the shelf life (microbial soundness) of the product. Such a solution was especially desirable for a centralized packaging facility where the meat would be shipped to distant locations. Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO was a new and novel approach that addressed these technological needs.

(Hunt Decl. ¶ 7).

39. Appellants demonstrate commercial success by comparing the sales of Appellants' "traditional" ActiveTech product, which included the claimed packaging but without the use of CO in the modified atmosphere,

with an “improved” ActiveTech product, using 0.4% CO in the modified atmosphere. (App. Br. 22-24; Sixth DelDuca Decl. ¶¶ 4-10).

40. Appellants indicate that commercial success is not directed to a cost advantage since the costs between the traditional ActiveTech product and the improved ActiveTech product are only fractionally different. (App. Br. 23-24; Sixth DelDuca Decl. ¶ 9).

41. Appellants indicate that commercial success is not due to advertising or marketing since there was a decrease in sales personnel, little or no advertising directed to the improved system, and overall advertising had decreased. (App. Br. 24; Sixth DelDuca Decl. ¶ 10).

42. Appellants argue that, since Appellants’ product was the only product allowed to use CO by the FDA since the 1962 regulation banning using CO in meat packaging, using CO in the modified packaging system of Carr and Breen would not have been obvious to one of ordinary skill in the art. (App. Br. 18-21; First DelDuca Decl. ¶ 9-14).

C. PRINCIPLES OF LAW

“On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of prima facie obviousness or by rebutting the prima facie case with evidence of secondary indicia of nonobviousness.”

In re Kahn, 441 F.3d 977, 985-86 (Fed. Cir. 2006) (emphasis omitted).

Establishing long-felt need requires objective evidence that an art-recognized problem existed in the art for a long period of time without solution and depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art.

Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 1382 (Fed. Cir. 1983) (“although the invention did achieve a result desirable

in all business which stock goods, there was no evidence that the industry perceived a decrease in inventory as a ‘long felt but unsolved need’”); *see also In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988) (“[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved.”). Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 496 (CCPA 1971)(“it was still incumbent upon appellant, if he wished by this method to rebut the inference of obviousness arising from the similarity of his process to the prior art, to bring forward evidence of his satisfaction of the need.”).

An applicant must produce hard evidence of commercial success, in particular, evidence of commercial success within the relevant market. *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1150-51 (Fed. Cir. 1983) (“The evidence of commercial success consisted solely of the number of units sold. There was no evidence of market share, of growth in market share, of replacing earlier units sold by others or of dollar amounts, and no evidence of a nexus between sales and the merits of the invention.”); *see also In re Huang*, 100 F.3d 135, 139-40 (Fed. Cir. 1996) (“Although Huang’s affidavit certainly indicates that many units have been sold, it provides no indication of whether this represents a substantial quantity in this market. This court has noted in the past that evidence related solely to the number of units sold provides a very weak showing of commercial success, if any.”).

Commercial success or other secondary considerations may presumptively be attributed to the claimed invention only where “the marketed product embodies the claimed features, and is coextensive with

them.” *Ormco Corp. v. Align Tech. Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006) (quoting *Brown & Williamson Tobacco Corp. v. Phillip Morris, Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000)). For example, “the asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art.” *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997); see also *In re Caveney*, 386 F.2d 917, 923 (CCPA 1967) (“It seems to us that appellant’s commercial success may well be due to those features of his ducts which are covered by the Walch patent. . . . Commercial success, in such circumstances, is no indication of patentability over the Walch device.”).

An affidavit fails if it recites conclusions without reciting the underlying facts to support those conclusions. *In re Thompson*, 545 F.2d 1290, 1295 (CCPA 1976) (affidavit related to secondary consideration of nonobviousness, notably copying, “sets forth no specifics and falls far short of constituting probative evidence.”); *In re Brandstadter*, 484 F.2d 1395, 1406 (CCPA 1973) (holding that affidavits directed to an issue of enablement fail in their purpose when they recite conclusions and few facts to buttress the conclusions).

D. ANALYSIS

Various factors may deter or inhibit a certain product idea from the marketplace, many of which are not related to innovation. Appellants’ evidence directed to FDA approval only proves that the technology was not used in the United States prior to such approval. However, since the technology was already known in the art and practiced in other countries (FF 11, 12, 14, 17, 20, 25, and 30), the regulations of the FDA are not sufficient

to show the technology was not obvious to one of ordinary skill in the art. Rather, the ban against the relevant technology, here using CO in a modified atmosphere package (FF 42), is evidence that the technology was known to one of ordinary skill in the art and would have been obvious to use, if the practice was allowed.

Further, the lack of FDA approval is not sufficient to show a long-felt need in the meat packaging industry. Rather, the evidence only demonstrates that FDA approval is required to practice the known technology in the United States. Though the Hunt Declaration provides some evidence of long-felt need for the claimed technology (FF 38), the Hunt Declaration lacks any objective evidence that the need was recognized and persistent among those skilled in the art, such as evidence of the failure of others to provide such a system. *Orthopedic Equip.*, 707 F.2d at 1382; *Gershon*, 372 F.2d at 538. Also, Hunt notes that the long-felt problem was solved by using CO in the modified atmosphere of Pactiv's traditional packaging system. (FF 38). Yet, using CO in a modified atmosphere was already known in the art and used for meat packaging in Norway. (FF 11, 12, 14, 17, 20, 25, and 30). As such, the need had already been satisfied by those who had used CO in a modified meat packaging. *Newell Cos.*, 864 F.2d at 768. Additionally, Hunt states that there was a long-felt need satisfied by Appellants' ActiveTech product, without providing any underlying facts to support his opinion testimony. *Thompson*, 545 F.2d at 1295; *Brandstadter*, 484 F.2d at 1406. As such, the Hunt Declaration is insufficient to overcome the prima facie case of obviousness otherwise established by the Examiner.

While Appellants provide evidence of commercial success (FF 39-41), Appellants fail to show the context of this success by indicating the market in which the improved ActiveTech product was sold. *Kansas Jack*, 719 F.2d at 1150-51; *Huang*, 100 F.3d at 139-40. Appellants only compare the sales of the improved ActiveTech product to their own traditional ActiveTech product, without disclosing what technology their competitors were using. (FF 39). Further, Appellants directly attribute the commercial success of the improved ActiveTech product to including CO in their traditional modified atmosphere packaging. (FF 39). However, since including CO in a modified atmosphere packaging was already known in the art (FF 11, 12, 14, 17, 20, 25, and 30), the commercial success of the improved ActiveTech product was not due to the merits of the claimed invention beyond what was readily available in the prior art. *J.T. Eaton*, 106 F.3d at 1571; *Caveney*, 386 F.2d at 923. Far more likely, the commercial success of Appellants' improved ActiveTech product is directly attributable to the fact that it was the only product that has a GRAS Notice favorably received by the FDA (FF 38), and thus was the only product on the U.S. market using CO in a modified atmosphere packaging. Finally, we agree with the Examiner that the commercial product does not embody all the claimed features of the invention. *Ormco*, 463 F.3d at 1311-12. In particular, the commercial product is not commensurate in scope with the claimed invention since claim 1 recites "about 0.1 to about 0.8 vol. % carbon monoxide," and the commercial product only has 0.4 vol. % CO. (FF 39).

Therefore, Appellants have not provided sufficient evidence of non-obviousness to rebut the prima facie case of obviousness established by the Examiner.

IV. CONCLUSION

In light of the above addressed issues, we

1. sustain the Examiner's rejection of claims 1-6, 8-11, 13-26, 28-30, 32-37, 87-90, 161, 162, and 164-171 under 35 U.S.C. § 103(a) as obvious over Carr in view of Woodruff, Koch, and Shaklai; and

2. sustain the Examiner's rejection of claims 1, 2, 5-10, 12-15, 18-23, 25-29, 31-34, 36-37, 87-90, and 161-171 under 35 U.S.C. § 103(a) as obvious over Breen in view of Woodruff, Koch, Shaklai, and Verbruggen.

V. DECISION

We affirm the Examiner's decision.

VI. TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal maybe extended under 37 C.F.R. § 1.136(a)(1)(v)(2008).

AFFIRMED

cam

NIXON PEABODY LLP
161 N. CLARK STREET
48TH FLOOR
CHICAGO, IL 60601-3213